

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
EASTERN DIVISION**

ANDREA HOLIFIELD,

Plaintiff,

v.

ELI LILLY AND COMPANY et al.,

Defendants.

CASE NO.: 3:06CV482 - ^V_P_M

JURY TRIAL DEMANDED

**ANSWER OF DEFENDANT ELI LILLY AND COMPANY
TO PLAINTIFF'S COMPLAINT**

Defendant Eli Lilly and Company ("Lilly"), by its counsel, hereby responds to plaintiff's Complaint as follows:

1. Lilly denies the allegations contained in Paragraph 1 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Complaint relating to whether plaintiff ingested Zyprexa®.

PARTIES

2. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 2 of the Complaint, except admits that (i) Lilly researched, tested, developed, manufactured, marketed, and sold Zyprexa® to independent pharmaceutical

wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with warnings approved by the Food and Drug Administration of the United States Department of Health and Human Services (“FDA”) regarding the risks and benefits of the medication; and (ii) Zyprexa is the brand name for olanzapine.

3. Lilly responds that:

3.1 Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 3.1 of the Complaint.

3.2 Lilly denies the allegations contained in Paragraph 3.2 of the Complaint, except admits that (i) Lilly is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Indianapolis, Indiana; (ii) at certain times, Lilly has been authorized to do business in the State of Alabama and this judicial district; (iii) Lilly researched, tested, developed, manufactured, marketed, and sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with warnings approved by the FDA regarding the risks and benefits of the medication; and (iv) National Registered Agents, Inc., 150 S. Perry Street, Montgomery, AL 36104 is a proper agent for service of process.

3.3 Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 3.3 of the Complaint.

JURISDICTION AND VENUE

4. Lilly denies the allegations contained in Paragraph 4 of the Complaint, except (i) Lilly admits that (a) at certain times, it has been authorized to do business in the State of Alabama and this judicial district; (b) it is amenable to service of process by an Alabama Court; and (c) the United States District Court for the Southern District of Alabama has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332; and (ii) Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 4 of the Complaint relating to codefendants.

5. Lilly denies the allegations contained in Paragraph 5 of the Complaint, except (i) Lilly admits that (a) at certain times, Lilly has been authorized to do business in the State of Alabama and this judicial district; and (b) Lilly researched, tested, developed, manufactured, marketed, and sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with warnings approved by the FDA regarding the risks and benefits of the medication; and (ii) Lilly is without knowledge or information

sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 5 of the Complaint relating to codefendants.

6. Lilly denies the allegations contained in Paragraph 6 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 6 of the Complaint relating to codefendants.

FACTUAL BACKGROUND

7. Lilly denies the allegations contained in Paragraph 7 of the Complaint, except admits that (i) Lilly researched, tested, developed, manufactured, marketed, labeled, and sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with warnings approved by the FDA regarding the risks and benefits of the medication; and (ii) Zyprexa is a psychotropic agent that belongs in the thienobenzodiazepine class of medications also known as “atypical antipsychotics.”

8. Lilly denies the allegations contained in Paragraph 8 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 8 of the Complaint relating to (i) Doctor Defendant; (ii) whether plaintiff used Zyprexa; and (iii) the condition(s) for which plaintiff sought treatment.

9. Lilly denies the allegations contained in Paragraph 9 of the Complaint.

10. Lilly admits that Zyprexa is a psychotropic agent that belongs in the thienobenzodiazepine class of medications also known as “atypical antipsychotics,” and is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 10 of the Complaint.

11. Lilly is without knowledge or information as to plaintiff’s meaning of the term “alternatives,” and therefore denies the allegations contained in Paragraph 11 of the Complaint.

12. Lilly denies the allegations contained in Paragraph 12 of the Complaint, except Lilly admits that (i) on September 30, 1996, the FDA approved Zyprexa for use in the “management of the manifestations of psychotic disorders,” based on data from clinical trials involving schizophrenic patients; (ii) on March 17, 2000, the FDA approved Zyprexa, in combination with Lithium or Valproate, for use in the “short-term treatment of acute manic episodes associated with Bipolar I Disorder; (iii) in 2004, the FDA approved Zyprexa for use as a maintenance monotherapy therapy for Bipolar Disorder; and (iv) in December 2003, the FDA approved Symbyax, a medication combining olanzapine and

fluoxetine, for the “treatment of depressive episodes associated with bipolar disorder.”

13. Lilly is without knowledge or information as to plaintiff’s meaning of the term “case reports in the literature,” and therefore denies the allegations contained in Paragraph 13 of the Complaint.

14. Lilly denies the allegations contained in Paragraph 14 of the Complaint, including Footnote 1 thereto, except (i) admits that medical literature reporting on medical research involving Zyprexa is published in multiple medical journals, but denies plaintiff’s description of the literature and “case reports” to the extent that it conflicts with such literature and “case reports” when read in context and in their entirety; (ii) denies the allegations contained in Paragraph 14 of the Complaint to the extent that the allegations are inconsistent with statements contained in the August 1999 issue of Clinical Drug Investigation when read in context and in their entirety; and (iii) denies the allegations contained in Paragraph 14 of the Complaint to the extent that the allegations are inconsistent with statements made at the October 2000 conference of the American Psychiatric Association when evaluated in context and in their entirety.

15. Lilly is without knowledge or information as to the “several reports” to which plaintiff is referring, and therefore denies the allegations contained in Paragraph 15 of the Complaint.

16. Lilly denies the allegations contained in Paragraph 16 of the Complaint to the extent that the allegations are inconsistent with statements contained in the December 2000 issue of the *British Medical Journal* when read in context and in their entirety.

17. Lilly denies the allegations contained in Paragraph 17 of the Complaint to the extent that the allegations are inconsistent with statements contained in the November 2001 issue of the *Journal of the American Medical Association* when read in context and in their entirety.

18. Lilly denies the allegations contained in Paragraph 18 of the Complaint to the extent that the allegations are inconsistent with the findings and conclusions of the Duke University Study when read in context and in their entirety.

19. Lilly denies the allegations contained in Paragraph 19 of the Complaint to the extent that the allegations are inconsistent with any statements or warnings made by the British Medicines Control Agency when read in context and in their entirety.

20. Lilly denies the allegations contained in Paragraph 20 of the Complaint to the extent that the allegations are inconsistent with any statements or warnings issued by the Japanese Health and Welfare Ministry when read in context and in their entirety.

21. Lilly denies the allegations contained in Paragraph 21 of the Complaint to the extent that the allegations are inconsistent with statements contained in the November 2003 issue of the *Journal of the American Medical Association* when read in context and in their entirety.

22. Lilly denies the allegations contained in Paragraph 22 of the Complaint to the extent that the allegations are inconsistent with statements issued in January 2004 by the panel comprising the American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, and North American Association for the Study of Obesity when read in context and in their entirety.

23. Lilly denies the allegations contained in Paragraph 23 of the Complaint to the extent that the allegations are inconsistent with any statements contained in the 2005 Physicians' Desk Reference when read in context and in their entirety.

24. Lilly denies the allegations contained in Paragraph 24 of the Complaint, except admits that (i) on September 30, 1996, the FDA approved Zyprexa for use in the "management of manifestations of psychotic disorder"; (ii) on March 17, 2000, the FDA approved Zyprexa, in combination with Lithium or Valproate, for use in the "short-term treatment of acute manic episodes associated with Bipolar I Disorder"; (iii) in 2004, the FDA approved Zyprexa for use as a

maintenance monotherapy therapy for Bipolar Disorder; and (iv) the FDA-approved labeling for Zyprexa states that “Safety and effectiveness in pediatric patients have not been established.”

ANSWERING COUNT I
[PHYSICIAN CONDUCT – MEDICAL NEGLIGENCE]

25. Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in the Complaint.

26. Lilly denies the allegations contained in Paragraph 26 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 26 of the Complaint relating to whether plaintiff was prescribed Zyprexa.

27. Lilly denies the allegations contained in Paragraph 27 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 27 of the Complaint relating to Doctor Defendant.

28. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 28 of the Complaint.

29. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 29 of the Complaint.

30. Lilly denies the allegations contained in Paragraph 30 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 30 of the Complaint relating to Doctor Defendant.

31. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 31 of the Complaint.

32. Lilly denies the allegations contained in Paragraph 32 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 32 of the Complaint relating to (i) codefendants; and (ii) plaintiff.

33. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 33 of the Complaint.

34. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 34 of the Complaint.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the

defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING COUNT II
[ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE]

35. Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in the Complaint.

36. Lilly denies the allegations contained in Paragraph 36 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 36 of the Complaint relating to codefendants.

37. Lilly denies the allegations contained in Paragraph 37 of the Complaint, except (i) admits that Lilly researched, tested, developed, manufactured, marketed, and sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication; and (ii) is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 37 of the Complaint relating to (a) codefendants and (b) the condition of Zyprexa when it reached consumers.

38. Lilly denies the allegations contained in Paragraph 38 of the Complaint, except is without knowledge or information sufficient to form a belief

as to the truth or falsity of the allegations contained in Paragraph 38 of the Complaint relating to codefendants.

39. Lilly denies the allegations contained in Paragraph 39 of the Complaint, except (i) admits that after receiving FDA approval to market Zyprexa, Lilly has marketed to physicians in accordance with applicable laws and regulations, with adequate communication of the known risks, and with adequate warnings commensurate with the risk and gravity of the possible side effects from its use; and (ii) is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 39 of the Complaint relating to fictitious defendants.

40. Lilly denies the allegations contained in Paragraph 40 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 40 of the Complaint relating to (i) codefendants; and (ii) whether Zyprexa was prescribed to plaintiff.

41. Lilly denies the allegations contained in Paragraph 41 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 41 of the Complaint relating to codefendants.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING COUNT III
[FAILURE TO WARN]

42. Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in the Complaint.

43. Lilly denies the allegations contained in Paragraph 43 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 43 of the Complaint relating to codefendants.

44. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 44 of the Complaint.

45. Lilly denies the allegations contained in Paragraph 45 of the Complaint.

46. Lilly is without knowledge as to plaintiff's meaning of the term "level of knowledge of an expert in the field," and therefore denies the allegations contained in Paragraph 46 of the Complaint, except is without knowledge or

information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 46 of the Complaint relating to codefendants.

47. Lilly denies the allegations contained in Paragraph 47 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 47 of the Complaint relating to (i) codefendants; and (ii) plaintiff.

48. Lilly denies the allegations contained in Paragraph 48 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 48 of the Complaint relating to codefendants.

49. Lilly denies the allegations contained in Paragraph 49 of the Complaint, except (i) admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing, warning, and sale of Zyprexa; Lilly denies that it breached such a duty; and (ii) is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 49 of the Complaint relating to codefendants.

50. Lilly denies the allegations contained in Paragraph 50 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 50 of the Complaint relating to codefendants.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING COUNT IV
[BREACH OF WARRANTY OF MERCHANTABILITY]

51. Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in the Complaint.

52. Lilly denies the allegations contained in Paragraph 52 of the Complaint, except (i) admits that Lilly researched, tested, developed, manufactured, marketed, and sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication; and (ii) is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 52 of the Complaint relating to codefendants.

53. Lilly denies the allegations contained in Paragraph 53 of the Complaint, except is without knowledge or information sufficient to form a belief

as to the truth or falsity of the allegations contained in Paragraph 53 of the Complaint relating to (i) codefendants; and (ii) plaintiff.

54. Lilly denies the allegations contained in Paragraph 54 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 54 of the Complaint relating to (i) codefendants; and (ii) whether plaintiff used Zyprexa.

55. Lilly denies the allegations contained in Paragraph 55 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 55 of the Complaint relating to codefendants.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING COUNT V
[NEGLIGENCE]

56. Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in the Complaint.

57. Lilly denies the allegations contained in Paragraph 57 of the Complaint, except is without knowledge or information sufficient to form a belief

as to the truth or falsity of the allegations contained in Paragraph 57 of the Complaint relating to codefendants.

58. Lilly denies the allegations contained in Paragraph 58 of the Complaint, except (i) admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing, labeling, warning, and sale of Zyprexa; Lilly denies that it breached such a duty; and (ii) is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 58 of the Complaint relating to codefendants.

59. Lilly denies the allegations contained in Paragraph 59 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 59 of the Complaint relating to codefendants.

60. Lilly denies the allegations contained in Paragraph 60 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 60 of the Complaint relating to codefendants.

61. Lilly denies the allegations contained in Paragraph 61 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 61 of the Complaint relating to codefendants.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING COUNT VI
[WANTONNESS]

62. Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in the Complaint.

63. Lilly denies the allegations contained in Paragraph 63 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 63 of the Complaint relating to codefendants.

64. Lilly denies the allegations contained in Paragraph 64 of the Complaint, except (i) admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing, labeling, warning, and sale of Zyprexa; Lilly denies that it breached such a duty; and (ii) is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 64 of the Complaint relating to codefendants.

65. Lilly denies the allegations contained in Paragraph 65 of the Complaint, except is without knowledge or information sufficient to form a belief

as to the truth or falsity of the allegations contained in Paragraph 65 of the Complaint relating to codefendants.

66. Lilly denies the allegations contained in Paragraph 66 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 66 of the Complaint relating to codefendants.

67. Lilly denies the allegations contained in Paragraph 67 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 67 of the Complaint relating to codefendants.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING COUNT VII
[FRAUD, MISREPRESENTATION AND SUPPRESSION]

68. Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in the Complaint.

69. Lilly denies the allegations contained in Paragraph 69 of the Complaint, except is without knowledge or information sufficient to form a belief

as to the truth or falsity of the allegations contained in Paragraph 69 of the Complaint relating to codefendants.

70. Lilly denies the allegations contained in Paragraph 70 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 70 of the Complaint relating to codefendants.

71. Lilly denies the allegations contained in Paragraph 71 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 71 of the Complaint relating to codefendants.

72. Lilly denies the allegations contained in Paragraph 72 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 72 of the Complaint relating to codefendants.

73. Lilly denies the allegations contained in Paragraph 73 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 73 of the Complaint relating to (i) codefendants; and (ii) plaintiff.

74. Lilly denies the allegations contained in Paragraph 74 of the Complaint, except is without knowledge or information sufficient to form a belief

as to the truth or falsity of the allegations contained in Paragraph 74 of the Complaint relating to (i) plaintiff, and (ii) codefendants.

75. Lilly denies the allegations contained in Paragraph 75 of the Complaint, except (i) admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing, warning, and sale of Zyprexa; Lilly denies that it breached such a duty; and (ii) is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 75 of the Complaint relating to codefendants.

76. Lilly denies the allegations contained in Paragraph 76 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 76 of the Complaint relating to codefendants.

77. Lilly denies the allegations contained in Paragraph 77 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 77 of the Complaint relating to codefendants.

78. Lilly denies the allegations contained in Paragraph 78 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 78 of the Complaint relating to codefendants.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

ANSWERING COUNT VIII
[FICTITIOUS PARTIES]

79. Lilly incorporates by reference, as though fully set forth herein, its answer to each and every allegation contained in the Complaint.

80. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 80 of the Complaint relating to the fictitious defendants.

81. Lilly denies the allegations contained in Paragraph 81 of the Complaint except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 81 of the Complaint relating to the fictitious defendants.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

PREAMBLE TO AFFIRMATIVE DEFENSES

Defendant Eli Lilly and Company, by its counsel, pleading in the affirmative and without prejudice to its other pleadings, states the following affirmative defenses. By virtue of asserting additional defenses, Lilly does not assume any burden of proof not otherwise legally assigned to it.

Lilly reserves the right to rely upon any of the following or any additional defenses to each claim for relief asserted by plaintiff to the extent that such defenses are supported by information developed through discovery or by evidence at trial.

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted against Lilly.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the statute of limitations.

THIRD AFFIRMATIVE DEFENSE

Venue is improper in this judicial district.

FOURTH AFFIRMATIVE DEFENSE

Some or all of plaintiff's claims are barred by the learned intermediary and/or sophisticated user doctrines. At all relevant times herein, plaintiff's prescribing physician(s) were in the position of learned intermediaries

and/or sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of Zyprexa.

FIFTH AFFIRMATIVE DEFENSE

The injuries, damages, and losses alleged in the Complaint, none being admitted, were caused in whole or in part by the negligence of plaintiff and/or others, over whom Lilly exercised no control, had no opportunity to anticipate or right to control, and with whom Lilly had no legal relationship by which liability could be attributed to it because of the actions of plaintiff and/or others.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's alleged loss, damage, injury, harm, expense, diminution, or deprivation alleged, if any, was caused in whole or in part by plaintiff's failure to exercise reasonable care and diligence to mitigate her alleged damages.

SEVENTH AFFIRMATIVE DEFENSE

Any and all damages alleged in the Complaint may have been caused by misuse of the product, failure to use the product properly, or negligent use of the product, and therefore the risk was assumed.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are preempted by federal law in that Zyprexa was manufactured and labeled in a manner consistent with the state of the art at the pertinent time and approved by the FDA.

NINTH AFFIRMATIVE DEFENSE

Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by plaintiff without substantially impairing the usefulness or intended purpose of the subject product.

TENTH AFFIRMATIVE DEFENSE

Some or all of plaintiff's claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comments j and k to Section 402A of the Restatement (Second) of Torts and/or the Restatement (Third) of Torts.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's breach of warranty claims are barred because plaintiff failed to give timely notice of any alleged breach of warranty to Lilly; plaintiff did not reasonably rely upon any alleged warranty; plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded, or modified.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by the applicable provisions of the United States Constitution, the Alabama Constitution, and/or the applicable Constitution of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. These provisions include,

but are not limited to, the First Amendment to the Constitution of the United States and/or Article I, Section 4 of the Constitution of the State of Alabama because Lilly's commercial speech regarding Zyprexa was neither false nor misleading.

THIRTEENTH AFFIRMATIVE DEFENSE

Lilly alleges that plaintiff was fully informed of the risks of the use of the product made the subject of this action by her treating physicians, and the informed consent given by plaintiff is pleaded as an affirmative defense.

FOURTEENTH AFFIRMATIVE DEFENSE

Upon information and belief, plaintiff had, or in the exercise of reasonable diligence would have had, full knowledge of the risks and possible adverse side effects pertaining to the use of the subject product, as well as the risks relative to the administering of the subject product into plaintiff's person, and all or part of the alleged injuries, damages, and/or losses (if any) sustained by plaintiff arose from and were caused by risks of which plaintiff was so aware, and such risks were accepted and assumed by plaintiff. Lilly possessed no duty to warn plaintiff, and, upon information and belief, possessed no ability to warn plaintiff directly, and had no contact with plaintiff. For these reasons, any recovery against Lilly should be diminished, reduced, offset, or barred in accordance with the principles of assumption of the risk.

FIFTEENTH AFFIRMATIVE DEFENSE

All products in any way connected with Lilly are defect-free and not unreasonably dangerous. Such products fully comply with the products liability standard of Alabama.

SIXTEENTH AFFIRMATIVE DEFENSE

Upon information and belief, some or all of the injuries alleged in the Complaint were caused by preexisting medical conditions, subsequent medical conditions, and the natural course of those conditions of plaintiff, by an idiosyncratic reaction, operation of nature, or act of God, for which Lilly is not responsible.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claim for punitive damages violates, and it is therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

a. It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

b. the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple

defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution;

c. the procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution;

d. the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution;

e. the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;

f. the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;

g. the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment to the United States Constitution;

h. an award of punitive damages to plaintiff in this action would constitute a deprivation of property without due process of law; and

i. the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

EIGHTEENTH AFFIRMATIVE DEFENSE

With respect to plaintiff's demand for punitive or exemplary damages, Lilly specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards, including but not limited to, those standards of limitation which arose in BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mutual Automobile Ins. Co. v. Campbell, 538 U.S. 408 (2003).

NINETEENTH AFFIRMATIVE DEFENSE

Punitive damages awards in Alabama are unconstitutional because they are penal in nature, yet defendants in civil action are not awarded the same procedural safeguards accorded to criminal and other defendants under the Fourth,

Fifth, Sixth, Eighth, and Fourteenth Amendments to the United States Constitution. Therefore, plaintiff cannot recover punitive damages.

TWENTIETH AFFIRMATIVE DEFENSE

Punitive damages awards in Alabama are not governed by any specific or adequate standards, are not based upon rational distinctions, do not serve any legitimate state interest, are necessarily vague and arbitrary, and therefore are in violation of the due process and equal protection provisions of the Fifth, Eighth, and Fourteenth Amendments to the United States Constitution, as well as those of Article I, Sections 1, 6, and 22 of the Alabama Constitution. Therefore, plaintiff cannot recover punitive damages.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims for punitive damages are barred by § 6-11-20 and § 6-11-27 of the Alabama Code.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Lilly affirmatively pleads and avers the protections afforded it by § 6-11-21 of the Alabama Code.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") is charged under the law with regulating prescription

drugs, including Zyprexa, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in plaintiff's Complaint would impede, impair, frustrate, or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

To the extent plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

TWENTY-FIFTH AFFIRMATIVE DEFENSE

The alleged injuries to plaintiff, if any, were caused, in whole or in part, by plaintiff's own contributory negligence, and are therefore barred.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Any verdict or judgment rendered against Lilly must be reduced by those amounts that have been, or will be, with reasonable certainty, paid to replace or indemnify plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation or employee benefit programs.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All or some of plaintiff's medical expenses have been paid by plaintiff's medical insurance carrier, or some other form of insurance, and plaintiff

is not entitled to recover said medical expenses pursuant to § 6-5-522 of the Alabama Code.

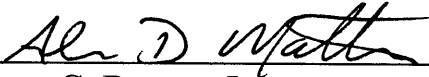
TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's purported allegations of misrepresentation and fraud do not comply with Rule 9(b) of the Federal Rules of Civil Procedure, in that they fail to state a cause of action as a matter of law because, among other deficiencies, plaintiff fails to plead with specificity any false misrepresentation as to a material fact and/or reliance on the part of plaintiff upon any such material fact.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

JURY DEMAND

Lilly demands a trial by jury for all issues in this action.



James C. Barton, Jr.

Bar Number: ASB-0237-B51J

Email: jbartonjr@jbpp.com

Alan D. Mathis

Bar Number: ASB-8922-A59M

Email: adm@jbpp.com

Attorneys for defendant

Eli Lilly and Company

JOHNSTON BARTON PROCTOR & POWELL LLP

2900 AmSouth/Harbert Plaza

1901 Sixth Avenue North

Birmingham, Alabama 35203

Telephone: (205) 458-9400

Facsimile: (205) 458-9500

OF COUNSEL

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by first class mail, postage prepaid, on this 26th day of May 2006 upon the following:

Joseph L. Tucker, Esq.
JACKSON & TUCKER, P.C.
Black Diamond Building
2229 First Avenue North
Birmingham, Alabama 35203

David P. Matthews, Esq.
ABRAHAM, WATKINS, NICHOLS
SORRELS, MATTHEWS & FRIEND
800 Commerce Street
Houston, Texas 77002

Peter Lusche, M.D.
3120 Frederick Road
Opelika, Alabama 36801



Of Counsel

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